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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,468

12/31/2003

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

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3763

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/749,468	<b>Applicant(s)</b> MOLINA ET AL.	
	<b>Examiner</b> VICTORIA P. CAMPBELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,8-14,17-25,27 and 29-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,8-14,17-25,27 and 29-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This is the initial Office Action following the Request for Continued Examination based on the 10/749468 application filed December 31, 2003. Claims 1-3, 5, 6, 8-14, 17-25, 27, and 29-49 as amended and newly presented in the Amendment dated May 11, 2009 are currently pending and considered below.

#### ***Drawings***

1. The drawings were received on May 11, 2009. These drawings are accepted.

#### ***Claim Objections***

2. Claim 11 is objected to because of the following informalities: line 2 contains an extra comma ( , ) after the word "material".
3. Claim 22 is objected to because of the following informalities: the second "material" at the end of the claim should be removed.
4. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 8 requires that the material of the first layer to be polyurethane. Applicant's specification only provides support for polyurethane comprising "inner layer 16" which, as indicated in Figure 1, is the innermost layer. Claim 32, from which claim 8 indirectly depends, requires the innermost layer to be comprised of copolyester ether (COPE).

Therefore the polyurethane layer can not be the innermost layer and therefore this particular embodiment is no longer enabled by applicant's specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 17-19 recite the limitation ""each second layer" or "the at least one second layer" or "the first layer". There is insufficient antecedent basis for this limitation in the claim. The examiner is unable to discern whether applicant erred in changing the dependence of claim 12 to be from claim 32 instead of claim 6, or if applicant intended to add the limitations of claim 6 to claims 17-19. For purposes of examination, the examiner has treated claim 12 as if still dependent upon claim 6 such that claims 17-19 have antecedent basis within claim 6.

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***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 32, 1, 5, 8, 10, 11, 6, 9, 33-37, 43-48; 38, 21-25, 27, 29-31, 39-42, 49; 2, and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/064909 A1 to Donohue et al.

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Regarding claims 32, 1, 5, 8, 10, 11, 6, 9, 33-37, 43-48; 2, and 3 Donohue et al disclose a tubing (1) for conveying fluidic media comprising at least one layer of COPE (Paragraph [0016]) where the at least one layer of COPE comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface. Further, Donohue et al disclose an inner layer having an open internal passage (3) and an intermediate layer for bonding the outer layer to the inner layer (2), wherein the intermediate layer comprises EVA (Paragraph [0020]) and the inner layer is comprised of polyurethane (Paragraph [0019]), wherein the outer and intermediate layers are free of PVC (Paragraph [0008]). COPE itself is a barrier to carbon dioxide, thus Donohue et al also disclose that the outer layer (of COPE) is a barrier to carbon dioxide. Further, the tubing comprises no more than one layer of COPE material (1), consists essentially of no more than one layer of COPE material (1), is free from other layers other than the at least one layer of COPE (1), the at least one layer of COPE is substantially free of other materials (1), and the inner surface is coated with a material for enhancing fluidic compatibility with the media (COPE). Donohue et al also disclose a second layer for bonding (2) between an inner layer (3) and a third layer comprised of COPE (1).

Regarding claims 38, 21-25, 27, 29-31, 39, and 49, Donohue et al disclose a process of making a tubing comprising selecting a COPE material and forming a tube (Paragraph [0021]) having at least one layer of COPE (1), wherein the COPE material comprises an outer peripheral surface and an inner peripheral surface of the tubing (see above). Further, Donohue et al disclose forming no more than one layer of the COPE (1), forming an inner layer (3), and forming an intermediate layer (2). Donohue et al

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further disclose that the outer layer is extruded COPE (1), the intermediate layer is extruded EVA (2), and that the layers can be singularly or co-extruded (Paragraph [0021]) and that the tubing is free from PVC (Paragraph [0008]) and the outer layer is a barrier to carbon dioxide (1).

However, Donohue et al do not explicitly teach that the inner layer is comprised of COPE. At the time of the invention, one having ordinary skill in the art of medical tubing would have recognized that COPE is a useful material in making medical grade tubing without the use of harmful plasticizers (Paragraph [0016]) and would therefore find it obvious to make any and all layers of a medical tubing out of COPE. Donohue et al further disclose that the intermediate layer is comprised of EVA (2). Donohue et al also fail to explicitly teach or disclose the use of a plurality of layers of COPE material or that EVA is used between each set of adjacent layers of COPE. However, the examiner notes that the use of multiple layers of COPE tubing interspaced with EVA is simply a duplication of parts already disclosed by Donohue et al (layers 1 and 2) and therefore would have been an obvious matter of design choice to one having ordinary skill in the art, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claims 40-42, Donohue et al disclose all the limitations of claim 38 as disclosed above, but fail to teach or disclose the extrusion of a plurality of layers of COPE material or that EVA is extruded between each set of adjacent layers of COPE. However, the examiner notes that the extrusion of multiple layers of COPE tubing

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interspaced with EVA is simply a duplication of parts within a process already disclosed by Donohue et al (layers 1 and 2; Paragraph [0021]) and therefore would have been an obvious matter of design choice to one having ordinary skill in the art, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

14. Claims 12-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al in view of USPN 6,248,093 B1 to Moberg.

Regarding the above claims, Donohue et al disclose the device of claim 6 as described above, but fail to teach or disclose its use in a system. Moberg teaches a drug delivery system (Fig. 1) combining a pump (101, 102, 103, 104), reservoir (105), and tubing (106) for the delivery of insulin (Col. 1, lines 14-16). Further, Donohue et al disclose that the material of the second layer of tubing is EVA (2), that each of the second and third layers is comprised of a single layer (Fig. 1), that the intermediate and outer layers are free of PVC (Paragraph [0008]) and that the outer layer is a barrier to carbon dioxide (1). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to use the tubing of Donohue et al in the medical system of Moberg because the tubing of Donohue et al does not contain plasticizers, which Donohue notes in Paragraph [0003] is detrimental to the delivery of insulin, such as that being delivered by the device of Moberg. Therefore, it would have been obvious to combine Donohue et al with Moberg to obtain the invention in the instant claims.



***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPN 5,984,912 to Niedospial et al discloses in Col. 5, lines 19-32 that copolyester ether is a suitable material for contacting medical fluids and is useful because it does not contain plasticizers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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